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23347	7590	12/29/2008	EXAMINER	
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RESEARCH TRIANGLE PARK, NC 27709-3398			3771	
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			12/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/533,708	DAVIES ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 December 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10, 14-33 and 36-42 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-10, 14-33 and 36-42 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 03 May 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 5, 2008 has been entered.

2. As directed by the amendment, claim 1 has been amended and claims 40-42 have been added. Claims 11-13 and 34-35 have been cancelled. Thus, claims 1-10, 14-33 & 36-42 are pending in this application.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4, 6-10, 16, 19-23 & 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dmitrovic et al., (WO 98/30262).

Dmitrovic et al., teach a container (Figure 3) having a first part (59) and a second part (63) and a hinge (64) through which the first and second parts are hingeably connected so that the parts are hingeably moveable relative to one another between a first position (closed) where the container is in a closed state and a second position (open) where the container is in an open state, wherein the first and second parts are

pivottally connected so that the first part is pivotable to different angular positions with respect to the second part when the container is in an open state including a first angular position where the first part is disposed behind the second part and wherein, when the first part is in the first angular position, the first and second parts are movable (capable of being moved) to a nesting state (when the dust cap is rotated 180 degrees and flipped up onto the body). See: page 9, lines 19-25 and figures 3-5.

Although Dmitrovic discloses a container that has a first part and a second part that can be pivoted and rotated relative to one another, Dmitrovic lacks the specific teaching that the first part and the second part nest together with the first part encapsulating a substantial portion of the second part, but with the container still in the open state.

Since Dmitrovic teaches that "it will be appreciated that this angle (the angle between the dust cap and lower body and the mouthpiece) can be substantially increased or slightly decreased according to the desired angle of rotation of the dust cover, lower body potion and dosing member" and the dust cover is capable of being flipped up toward the rear of the body, it would have been an obvious modification to one having ordinary skill in the art to rotate the lower body portion and dust cover 180 degrees from the mouth piece and then flip the dustcover upward to form a compact, easy to hold container that nests the body inside the dust cover while delivering medicament to a user. Since applicant has not defined the term substantial, the common dictionary definition has been applied.

Webster's Third World Dictionary of American English, Third College Edition, defines substantial as "considerable; ample; large." Thus, it is the examiner's position that by rotating the dust cover and flipping it up, a substantial (ample) amount of the container would be encapsulated by the cover.

Modifying the back of the container to have a snap fit configuration, similar to the snap fit configuration shown in the front of the container is a design modification that would be obvious to a skilled artisan. One would be motivated to form such a configuration in order to form a cap that functions like a conventional cap. Conventional caps are sized and shaped to fit over the top of a container and then be removed and stored on the bottom of a container, so as to keep the cap and container together during use, but storing the cap out of the way (i.e. a pen). Thus, modifying the shape of the container to allow the cap to be snap fit to back of the container is a design consideration within the skill in the art, as it has been held that a change in the shape of a prior art device is a design consideration within the skill of the art. *In re Dailey*, 357 F.2d 669, 149 U USPQ 47 (CCPA 1966).

Dmitrovic et al., show the first and second parts as being closed (Figure 3) with a ridge portion on (80) for locking the container in a closed state, thus meeting the limitations of claims 2, 3, and 6.

Regarding claims 4 and 7, Dmitrovic discloses a first and second parts interengage and lock to form a snap fit connection between respective lip structures of the first and second parts (See: figure 1, where lip at the top of 63 contacts the body).

In regard to claims 8-10 & 19, Dmitrovic et al., shows that the second part (63) as being pivotally hinged to the first part (59). The Dmitrovic et al., reference teaches that the hinge is statically mounted to the first part (59) and pivotally mounted to the second part (63) and that the first and second parts can pivot and rotate around the container (Figure 4). Dmitrovic et al., teach moving the second part to both an open and a closed state and that in use, in the open position, the second part (63) is rotated to the side of the container (Figure 5) to allow administration of the drug contained within the container. See: page 4, line 21 -page 5, line 8 and page 11, line 23 – page 12, line 9.

Dmitrovic et al., teach that the drug is contained in an inner part (56) and that the inner part (56) is adapted to hold the product in the container, thus meeting the specific limitations of claim 19. See: page 4, line 21 - page 5, line 21.

Regarding the limitations of claims 21-23, modifying the back of the container to have a snap fit configuration, similar to the snap fit configuration shown in the front of the container is a design modification that would be obvious to a skilled artisan. One would be motivated to form such a configuration in order to form a cap that functions like a conventional cap. Conventional caps are sized and shaped to fit over the top of a container and then be removed and stored on the bottom of a container, so as to keep the cap and container together during use, but storing the cap out of the way (i.e. a pen). Thus, modifying the shape of the container to allow the cap to be snap fit to back of the container is a design consideration within the skill in the art, as it has been held that a change in the shape of a prior art device is a design consideration within the skill of the art. In re Dailey, 357 F.2d 669, 149 U USPQ 47 (CCPA 1966).

Regarding claim 40, Dmitrovic et al., teach a container (figure 3) having a first part (59), a second part (63) and a hinge (64) through which the first and second parts are hingeably connected so that the parts are hingeably movable relative to one another between a first position (closed) where the container is in a closed state and a second position (open) where the container is in an open state; wherein the first part is pivotable relative to the second part to different angular positions (figures 3-5) in the open state of the container, including a first angular position where the first part is disposed behind the second part (figure 5); wherein the first and second parts are movable (capable of being moved) to a nesting state (when the dust cap is rotated 180 degrees and flipped up onto the body). As discussed above, it would have been an obvious modification to one having ordinary skill in the art to rotate the lower body portion and dust cover 180 degrees from the mouth piece and then flip the dustcover upward to form a compact, easy to hold container that nests the body inside the dust cover while delivering medicament to a user and once the first part is rotated around and flipped up into a nesting state, an interference fit (friction where the dust cap contacts the body assembly) is formed between the first part and the second part to releasably fasten (via friction) the first and second parts in the nesting state.

Regarding claim 41, Dmitrovic et al., teach a first part and a second part with concave and convex portions that would interact to form a nesting state and it has been held that a change in the shape of a prior art device is a design consideration within the skill of the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). Thus, the modification of the device disclosed by Dmitrovic to have the second part with a convex

rear surface and a first part with a concave cavity being configured to slidingly receive the convex rear surface of the second part to establish the nesting state is merely a shape change that is ell within the skill of the art.

5. Claims 5, 24-27, 30-33 and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dmitrovic et al., (WO 98/30262) as applied to claims 1-3, and 19-23 above, and further in view of Howlett (6,062,214).

6. Dmitrovic et al., teaches all the limitations of claim 5, except the hinge being a living hinge.

Howlett teaches an inhaler for the aerosolized dispersion of medicaments and a cover (15) making contact with the lip of the mouthpiece (14) to close and protect the mouth piece. Howlett teaches the cover and body being connected by a living hinge (27). See: col. 2, lines 55-65; col. 3, lines 17-21 and Figure 1.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the hinge disclosed by Dmitrovic et al., with the living hinge, as taught by Howlett, in order to obtaining a hinge and cover that could be integrally formed of plastic while allowing the cover to close tightly using the lip surfaces of the cover and body.

Regarding claims 24-27, Dmitrovic discloses a container (56) in which a product (medicament) can be packaged, as taught by Howlett (12) with contents to be dispensed.

Dmitrovic discloses a dispenser with a dispensing mechanism (53) for dispensing the contents of the package and the dispensing mechanism operates through relative

movement between the dispenser and the package when the dispenser is fixedly secured in the outer structure and Howlett discloses a container in which the dispenser has a delivery nozzle through which the contents of the package are dischargeable.

Regarding claims 36-39, when the dust cap on the inhaler device is turned 180 degrees from the mouthpiece and the dust cap is flipped upwards, it would provide a concave/convex nesting state as claimed with the dust cap slidable engaging the body (as it makes contact with the body), and friction would provide an interference between the dust cap and body. See: figures 3-5 and page 9, line 20 - page 10, line 2.

7. Claims 14, 15, 17, 18 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dmitrovic et al., (WO 98/30262) taken together with Howlett (6,062,214) and further in view of Rand et al., (WO 98/56444).

The combined references above teach a container for holding an aerosol that has a cover that can be opened and pivoted in a manner to prevent contamination during normal use, as described above; however, the combination of references lacks the specific teaching of providing a container with reading feature and dose counter as claimed in claims 14, 15, 17, 18 and 29 or the intranasal dispenser as claimed in claim 28.

Rand et al., teach an inhaler comprising an external housing (1) with counter mechanism (13) and a window for viewing said counter mechanism through the rear of the housing (20). The Rand et al., reference teaches that the dispensing mechanism is useful in the treatment of respiratory disorders and that the counter allows the user to view the number of doses remaining in the container before the contents have been

exhausted. Moreover, the Rand et al., reference teaches that metered dose inhalers are well known for delivering medicaments to the mouth and the nose for treatment of respiratory disorders. See: page 1, lines 1-34; page 4, lines 1-9; page 5, lines 24-35; page 6, lines 26-33 and Figures 1 and 7.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the aerosol device as taught by the combined references above by adding a viewing window for reading the number of doses remaining in the inhaler, as taught by Rand et al., because of the reasonable expectation of obtaining an inhaler which provides a user with information about the remaining life of the product.

8. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dmitrovic et al., (WO 98/30262), as applied to claim 40 above, and further in view of Greenwood et al., (6,615,827).

Dmitrovic discloses a container with all the limitations of claim 42 except the second part having a rear surface that includes a window for viewing the contents of the container and a first part that is transparent. However, Dmitrovic discloses “future possible modifications to the device described include incorporation of a suitable dose counting mechanism to give the user an indication of the amount of powder remaining in the device.” See: page 10, lines 4-6.

Greenwood teaches an inhaler (figure 1) with a longitudinal indicator device (30) on its surface.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the inhaler device disclosed by Dmitrovic by placing a longitudinal indicator, as taught by Greenwood, on the rear of the body of the inhaler in order to provide the user with an indication of the amount of powder remaining in the device.

Regarding the transparency claim limitation, it would have been an obvious design consideration to incorporate either a viewing window or to form the cover of a transparent material in order to view the indicator device in both an open or a closed state.

Response to Arguments

9. Applicant's arguments, filed December 5, 2008, regarding claims 1-10, 14-33 and 36-42 have been fully considered but they are not persuasive.

Regarding applicant's argument that Dmitrovic does not render independent claim 1, or the claims that depend therefrom, *prima facie* obvious, because Dmitrovic does not teach or suggest a device being structurally capable of nesting, the examiner respectfully disagrees.

10. The test for obviousness is not that the claimed invention must be expressly suggested in the references; rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of

ordinary skill in the art without any specific hint or suggestion in a particular reference.

In re Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

In the instant case, it would be an obvious design consideration to rotate the dust cap 180 degrees and flip it up to make contact with the container body in order to provide a device that would be easier to use, could be held and actuated with one hand, and that would secure the cap in a fixed position while a person is inhaling. Since the use of inhalers requires coordination of administering the medicament from an inhaler and inhaling at a constant rate (for best results), forming a container that is more compact and easier to use (with less moving part during actuation) would be desirable and obvious to the skilled artisan. On a final note, having a moveable duct cap that extends out would create a greater chance of mechanical breakage. Thus, by moving the dust cap 180 degrees and flipping it up the dust cap would be more secure as it would be in contact with the body of the device, thus, giving the device an added benefit of making the dust cap less likely to break during use or accidental dropping of the inhaler.

Regarding applicant arguing that Dmitrovic teaches away from the configuration suggested by the examiner, the examiner respectfully disagrees. Simply because there are differences in Dmitrovic does not establish that it "teaches away" from the suggested configuration. In fact, Dmitrovic teaches that the angle can be "substantially increased" and does not give a limitation as to the amount it can be increased. Thus, a skilled artisan would clearly recognize by rotating the dust cover 180 degrees and

flipping it up against the body of the container, a compact, easy to manipulate configuration of the device could be obtained.

Regarding applicant's argument that the dust cover cannot encapsulate a substantial portion of the main body portion, the examiner respectfully disagrees. First, applicant has not defined the term substantial. Thus, the Webster's Third World Dictionary of American English, Third College Edition, defines substantial as "considerable; ample; large." It is the examiner's position that by rotating the dust cover and flipping it up, a substantial (ample) amount of the container would be encapsulated by the cover. Moreover, narrowing the rear of the body is a design consideration within the skill in the art, as it has been held that a change in the shape of a prior art device is a design consideration within the skill of the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

11. Applicant's arguments filed December 5, 2008, regarding the 35 USC 103(a) rejection of claims 4, 5, 7, 21, 24-27 and 30-33 as being unpatentable over Howlett in view of Dmitrovic (WO 98/30262), have been fully considered but they are not persuasive.

Applicant argues that neither Howlett nor Dmitrovic disclose, teach or suggest that a Howlett does not disclose, teach, or suggest that the first part of a container is movable in the open state to a nesting state where the first part and the second part nest together with the first part encapsulating a substantial portion of the second part.

As described above, Dmitrovic was used to teach a device with the first part (59) of a container (figure 3) that is movable (capable of being moved) in the open state

(when the 63 is opened and rotated 180 degrees) to a nesting state (by flipping up the dust cover) where the first part and the second part nest together with the first part encapsulating a substantial (ample) portion of the second part.

12. Applicant's arguments filed December 5, 2008, regarding the 35 USC 103(a) rejection of claims 14, 15, 17, 18 and 28-29 as being unpatentable over Howlett in view of Dmitrovic (WO 98/30262) and further in view of Rand et al., (WO 98/56444), have been fully considered but they are not persuasive.

Applicant argues that Rand does not disclose, teach or suggest that a first part and a second part of a container are configured to nest together in a nesting state when the first part is in the first angular position.

As described above, Dmitrovic was used to teach a device with the first part (59) of a container (figure 3) that is movable (capable of being moved) in the open state (when the 63 is opened and rotated 180 degrees) to a nesting state (by flipping up the dust cover) where the first part and the second part nest together with the first part encapsulating a substantial (ample) portion of the second part.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lewis (2004/0112896) and Kiziol (3,734,076) disclose containers with rotating hinged lids.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Danton DeMille/
Primary Examiner, Art Unit 3771

/Clinton Ostrup/
Examiner, Art Unit 3771